

***Remarks***

Claims 1, 15-49, 54-56, 62, 63, and 65-73 are pending in the application, with claims 1, 16, 17, 49, 55, 56, 63, and 67, being the independent claims. Claims 2-14, 50-53, 60, 61, 64 and 57-59 were cancelled by previous amendment. Claims 1, 15, 49, 54-56, 62, 63, 65 and 66 were previously withdrawn from further consideration as being drawn to a non-elected invention, there allegedly being no allowable generic or linking claim.

Based on the following remarks, Applicants respectfully request that the Office reconsider all outstanding rejections and that they be withdrawn.

***Interview Summary***

Applicants would like to thank Examiner Chong for the courtesy he extended during the interview with Applicants' representatives, John Covert and Marsha Rose, on Monday, September 22, 2008.

During the interview, the rejection of claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-8, 11, 14, 15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2, in the Office Action of July 28, 2008, was discussed. Applicants thank Examiner Chong for indicating during the interview that he would request a second opinion regarding this issue.

Examiner Chong opined during the interview that there may be potential enablement issues with regards to the type of microbial infection treated and the dosage amounts and requested Applicants review the claims and specification.

Applicants have reviewed the specification and claims, and submit that the specification provides sufficient information to enable a person having ordinary skill in

the art to make and use the currently claimed invention without undue experimentation.

First, in paragraph [0237] of the application as filed, Applicants describe the types of microbial infections which may be treated with the oligomers of Formula II. Second, in paragraphs [0299]-[0300] of the application as filed, Applicants indicate the routes by which the oligomers of Formula II may be administered to treat a microbial infection in an animal. Third, in paragraphs [0301]-[0312] of the application as filed, Applicants provide guidance as to how the oligomers of Formula II may be formulated as a pharmaceutical composition. Finally, Applicants provide multiple examples of how to test whether a particular oligomer will be effective for use in the claimed methods. (*See e.g.*, Examples 5, 9, and 10.)

Thus, the specification provides sufficient information to enable a person having ordinary skill in the art to make and use the currently claimed invention without undue experimentation. Applicants invite Examiner Chong to telephone the undersigned to discuss this issue in more detail.

***Obviousness-Type Double Patenting Rejection***

Claims 16-48 and 67-73 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 4-8, 11, 14, 15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2 ("the '102 patent"). The Examiner alleges that:

It would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer to an animal infected with a microorganism a pharmaceutical composition comprising a compound of formula I or II as disclosed by the referenced claims.

A person of ordinary skill in the art would have been motivated to administer to an animal infected with a microorganism a pharmaceutical composition comprising an oligomer of formula I because: (1) of general teaching that the disclosed oligomers inhibit the growth of

microorganisms on a surface; (2) interpreting the term "substrate" broadly includes any surface in need of killing microorganism, such as the skin or internal organs; and (3) animals with a microbial infection is a species within the broad genus of substrates. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a microbial infection in an animal by administering a composition comprising an oligomer of formula I.

(Office Action, page 4). Applicants disagree with the Examiner's rejection for at least the reasons below.

Regarding double patenting, the Federal Circuit articulated two inquiries which must be made in determining whether a rejected claim is unpatentable under the judicially created doctrine of obviousness-type double patenting, also known as nonstatutory double patenting. *General Foods v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278 (Fed. Cir. 1992)(citing *In re Vogel*, 422 F.2d 438, 439 (C.C.P.A. 1970)); *see also*, *Manual of Patent Examining Procedure*, 8th edition, revision 6, § 804, p.800-21 (September 2007) ("MPEP"). The court defines these inquiries as follows:

Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting.

*General Foods*, 972 F.2d at 1278.

In addition, the court emphasized that where a "rejected claim defines *more* than an obvious variation, it is *patentably distinct*." *Id.* (emphasis in original).

Because the currently claimed invention is different from the invention encompassed by claims 1, 4-8, 11, 14, 15, 20-22, and 26, of the '102 patent, the same invention is not being claimed twice. Claims 16-48 and 67-73 of the above-captioned application are directed to a method of treating a microbial infection in an animal, the method comprising administering to the animal an effective amount of a pharmaceutical

composition comprising an amphiphilic oligomer of Formula II and a pharmaceutically acceptable carrier or diluent. A microbial infection, as encompassed by the presently claimed invention, refers to an "invasion and multiplication of microorganisms in body tissues." Dorland's Medical Dictionary for Healthcare Consumers, [http://www.mercksource.com/pp/us/cns/cns\\_hl\\_dorlands\\_split.jsp?pg=/ppdocs/us/common/dorlands/dorland/four/000053439.htm](http://www.mercksource.com/pp/us/cns/cns_hl_dorlands_split.jsp?pg=/ppdocs/us/common/dorlands/dorland/four/000053439.htm) (last visited October 22, 2008) (Exhibit A). Thus, claims 16-48 and 67-73 are directed to the use of the oligomers of Formula II to treat the invasion and multiplication of microorganisms in body tissues of an animal.

In contrast, claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent are directed to a polymer or oligomer of a specific formula. Additionally, claim 26 of the '102 patent is directed to a method of killing microorganisms, the method comprising the steps of providing a substrate having disposed thereon a contact-killing, facially amphiphilic polymer or oligomer of claim 1, claim 14 or claim 20 and placing the polymer or oligomer disposed thereon on the substrate in contact with a microorganism to allow formation of a pore in the cell wall of the microorganism.

Applicants submit that, contrary to the Examiner's statements, claims 16-48 and 67-73 of the current application would not have been obvious in light of claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent for at least the following reasons.

First, claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent are directed to facially amphiphilic polymers and oligomers of a specific formula. Because claims 1, 4-8, 11, 14, 15, 20-22 of the '102 patent are directed to facially amphiphilic polymers and oligomers of a specific formula, a person of ordinary skill would not necessarily expect that these compositions, based solely upon the language of the claims, could be administered to an animal treat a microbial infection.

Second, claim 26 of the '102 patent is directed to the use of a polymer or oligomer of a specified formula to kill microorganisms by attaching or applying the polymers or oligomers to a substrate, such as wood, cloth and metal. A polymer or oligomer that functions as an antimicrobial agent, when attached or applied to a surface, such as wood or cloth, would not necessarily be effective in treating a microbial infection in an animal when administered to the animal, *e.g.*, by parenteral injection of a pharmaceutical composition, as recited by claims 16-48 and 67-73 of the current application. In fact, as evidence of the nonobviousness of claims 16-48 and 67-73, Applicants submitted a Declaration on June 25, 2008, by David P. Nicolau, Pharm.D., FCCP, an expert in the field of infectious diseases, in which Dr. Nicolau stated that "a person of ordinary skill in the art would not necessarily expect a polymer shown to function as an antimicrobial agent when attached to or incorporated into an object to be effective in treating a microbial infection in an animal." Declaration under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP ("the Nicolau Declaration"), pp. 3-4, ¶8.

Accordingly, Applicants submit the rejection of 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting has been overcome and respectfully request that the Examiner reconsider and withdraw the rejection.

***Provisional Obviousness-Type Double Patenting Rejection***

Claims 16-48 and 67-73 were provisionally rejected under obviousness-type double patenting as being unpatentable over claims 49-53 of co-pending U.S. Appl. No. 11/980,785, the divisional application of the above-captioned application. Applicants disagree. However, solely in the interest of expediting prosecution, Applicants are filing

a terminal disclaimer over co-pending Application No. 11/980,785 herewith. Therefore,

Applicants submit this rejection has been rendered moot.


Accordingly, Applicants respectfully request that the preceding rejection be withdrawn.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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